Data Sharing and Intellectual Capital Working Group Teleconference

August 19, 2004	2:00 pm EDT
Attendees:	Jefferson University: Jack London Oregon Health and Science University: Ed Quick University of Iowa: Tom Casavant University of Minnesota: Don Connelly Washington University—Siteman: Mark Watson Fox Chase: Amin Chisti; Pat Harsche-Weeks University of Pennsylvania: David Fenstermacher; Howard Bilofsky NCI - Wendy Patterson; Leslie Derr BAH - Phan Winter
Introduction	Wendy Patterson opened the meeting, reviewed the agenda, and asked whether the group had comments on the notes from the 8/5/04 teleconference. Howard Bilofsky asked whether the meeting minutes had also been sent to DSIC WG IP contacts. Wendy responded that they have not. She would first like to have DSIC WG participants review the meeting notes and then send the minutes to their respective IP POCs for comments when appropriate.
DSIC WG Participation	Wendy observed that the DSIC WG has been active over the last few months but that some members may have been reluctant to participate since their institutions had not yet executed contracts for caBIG activities. Now that negotiations for most contracts have been completed, she thought that it was important to restate NCI's expectations for DSIC WG member participation. First, she noted an inconsistent level of member attendance, including members serving as liaisons, which has made it difficult to obtain comprehensive updates on other WS/WG activities. Consequently, she recommended changing the designations of liaisons to members who can consistently attend both DSIC WG and other WS/WG teleconferences. In addition, DSIC WG members need to notify Phan if they will be absent from scheduled teleconferences and designate a

	substitute. Second, Wendy stated that group members would need to start assuming more responsibility for DSIC WG activities. Routine WG activities such as setting meeting agendas and leading discussions will be delegated in the near future. Phan will follow up with individual members to confirm their interest in continuing to participate in the DSIC WG. One member asked whether the Statements of Work would define the level of participation and correlate specific sets of DSIC WG activities to SOW deliverables. Wendy responded that she and Phan would follow up off line to help clarify this issue. Howard asked whether qualifications and expertise in data sharing issues were required for participation in the DSIC WG. Wendy responded that members' lay experience in tandem with input from their IP POCs when needed would be appropriate. She recommended that group members communicate regularly with their IP contacts to keep them involved in DSIC WG activities. Wendy closed the discussion by emphasizing the importance of reviewing meeting notes, actively participating in discussions, and assisting in agenda development for future meetings.
Report from Liaisons	**Architecture:** Robert Robbins (FHCRC) and Vincent Yau (OHSU) were absent. **Training:** Ed Quick (OHSU) – This WG last met on August 11th. Both the Developer SIG and Adopter SIG are working on video conferencing options and plans for developing training documents. The Communication SIG is under reconstruction. The Training Group also discussed its plans for a face-to-face meeting to be held in conjunction with the APII meeting in October. **Strategic Planning:** Michael Becich (University of Pittsburgh) was absent. **Integrative Cancer Research:** Terry Braun (University of Iowa – Holden) was absent. **Clinical Trials:** Don Connelly (University of Minnesota) - This WG had a face-to-face meeting in Pittsburgh in July, which was very productive. The five SIGs made presentations to the entire group in 2-hour plenary sessions each. The participation level was high and the group decided on a number of action

	items. However, since the follow up teleconference held last week had low attendance, many action items are still outstanding. Don noted that this WS has made progress in setting priorities but to date has not generated data sharing issues for consideration by the DSIC WG. City of Hope will host the next CT WS face-to-face meeting, which is tentatively scheduled for mid October. **CT SIG updates:** **Structured Protocol SIG** – This SIG plans to redefine and clarify the vision for protocols with humans and computers. (this seems odd as written, but I don't remember the point that was presented and I'm not sure what the change should be) **Lab Interface** – Investigators from Sloan Kettering recently made a presentation that raised a HIPAA-related data sharing issue: how long can a study keep collecting data on consented patents and what kinds of data may be kept? **Compatibility** – This SIG will continue to consider how to define caBIG compatibility. **CTMS/CDUS** – A few NCI representatives are active in this SIG. They are setting goals for setting up communications tools. Joyce Niland gave a presentation on how to prioritize activities. **Tissue Banks and Pathology Tools Workspace:** Mark Watson (Washington University - Siteman) The TBPT WS had its last teleconference on August 17th. A face-to-face meeting is likely to be scheduled in October. This meeting will try to assemble the experts in tissue banks to discuss use cases and will be held at a Mid-Atlantic location. One of the TBPT SIGs is beginning to address IRB issues. This group will ask members attending the October face-to-face meeting to present specimen bank documents used at their centers. The TPBT WS may subsequently prepare a white paper that recommends model provisions to help with specimen banking. **Vocabulary/CDE Workspace:** Michael Becich (University of Pittsburgh) was absent.
Data Sharing Survey Development	Wendy discussed the feedback received during the Strategic Planning WG teleconference held on August 16th. She reported a suggestion from John Casagrande to ask survey respondents

	to identify the parties with which their centers have existing agreements. In this way the DSIC WG could gather information that might reveal common relationships between participating institutions and certain companies. Certain members of the DSIC group thought that it would be better to focus on individual relationships rather than try to develop an aggregate relationship between the caBIG community and certain vendors, which is where such information might lead. It was also observed that companies do not like to have the terms of their agreements disclosed. Wendy noted that the overall goal is to develop model provisions and best practices guidance for centers that can be publicly disseminated. Leslie Derr commented that the Strategic Planning WG might also have been suggesting was that since the DSIC WG is developing a survey, the group might as well solicit as much information as possible and try to determine whether there is commonality among caBIG centers in terms of their relationships with vendors. Another member observed that the centers might respond as requested but that industry may not be willing to cooperate if companies thought that they were being required to negotiate a single agreement with the entire cancer community. Pat Harsche-Weeks pointed out however that there is some precedent for developing a template agreement. She mentioned the example of a uniform clinical trial agreement that was developed by a large group of cancer centers after resolution of a number of issues, including indemnification, publication rights, legal status, etc. The group concluded that it could adopt John Casagrande's suggestion to ask that vendor identification information be reported, but that the group would need to guard that data once it was obtained.
IRB and HIPAA Issues for the caBIG Community	Wendy Patterson introduced the topic of compliance with IRB and HIPAA requirements, which is perceived as a pressing concern by the caBIG community. David Fenstermacher (U Pennsylvania), a member of several caBIG WS & WGs, participated in the discussion. David has volunteered to assist the DSIC WG to identify the issues and articulate solutions. David noted that part of the difficulty is the fact that the HIPAA privacy regulation only provides general guidelines and does not specify procedures that could be used by individual cancer

centers. He outlined the problems for the caBIG community:

- how to transfer human subject data?
- what is the appropriate breadth of data?
- what is the length of time data can be held?
- how much de-identified data will be allowed on the Grid network?

He noted that there is a need to develop tools for a clinical trial management system. He stated that the Translation SIG of the ICR WS also needs to deal with de-identification issues. Since the issues cut across the needs of the caBIG WS/WGs, he recommended that these issues need to be addressed at the Strategic Level within caBIG.

David will serve as a liaison between the ICR Domain WS and the DSIC WG to help focus the discussion on addressing the meaning of being HIPAA-compliant and developing caBIG guidelines for HIPAA compliance. He recognized that it may not be realistic to prepare one document to serve all caBIG centers since each institution has own its own procedures for HIPAA compliance. However, he thought it would be important to understand each institution's procedures and develop best practices guidance for participating caBIG centers and their IP contacts in order to ensure adequate data flow across the Grid.

Wendy asked how the DSIC WG could help with this process. David responded that these issues relate to data sharing and therefore should be addressed centrally by a cross cutting WS or Strategic Level WG within caBIG rather than piece-meal by individual WS/WGs.

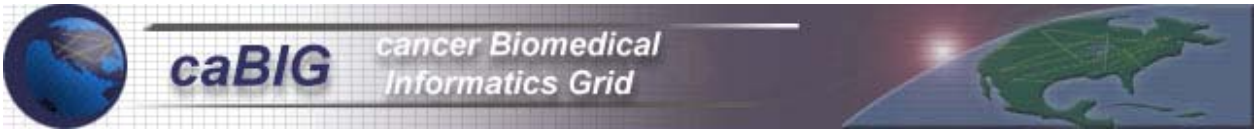
Howard Bilofsky commented that the data sharing practices of caBIG participants will reflect on caBIG as a whole. He supported the idea of a central place within caBIG where best practices can be developed and disseminated. He thought that the group would likely need to consult outside expertise in developing the best practices. Wendy asked Howard to start compiling a list of issues and potential experts to address such issues and circulate the list so that other DSIC WG members can add to the list. The group can then use this list as a basis for inviting outside consultants to discuss the issues with the DSIC WG. Pat Harsche-Weeks noted that it would be important to have input from the private sector and pointed out that there

are lots of experts on HIPAA and informed consent issues who could assist with the building of individual databases that conform to regulatory requirements.

David suggested that the DSIC WG permit flexibility in the group's structure so that other caBIG members can participate ad hoc as issues of interest arise. The DSIC WG can then serve as a "home" for these issues where caBIG participants can present their concerns and the group can respond as needed.

David also cautioned that the "best practices" document should be a living document since over time new issues regarding HIPAA compliance will arise and the caBIG guidance will need to be updated. Wendy added that caBIG cannot certify that a particular center is HIPAA-compliant but that the group can strive to develop "HIPAA-friendly" standards. Pat pointed out periodic audits do provide individual cancer centers with some measure of certification for HIPAA-compliance.

Mark Watson suggested that the group explore whether caBIG activities are exempt from HIPAA regulations before developing guidelines. He thought that the group should collect a set of cases and scenarios to establish a general framework for developing guidelines. Wendy pointed out that the draft data sharing survey has outlined several likely caBIG scenarios. She offered to circulate a separate document containing these scenarios, which could be updated to include additional cases. David suggested that the DSIC WG ask the caBIG leadership how far it wants to go in addressing HIPAA compliance issues. Along these lines, he noted that the clinical trial management community has recently talked a lot about the need for universal identifiers, which would track patient research subjects for long periods through different studies. If the caBIG leadership determined at some point in the future that the use of universal identifiers were a priority, then the relevant caBIG WS/WGs would need to start thinking about developing the necessary tools to meet this objective. Howard thought that it might be possible to devise ways to identify patients from different institutions studies without violating HIPAA regulations. However, he agreed that the DSIC WG would need direction from the caBIG leadership before prioritizing this issue.



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Action Items:	Name Responsible	Action Item	Date Due	Notes
	Howard Bilofsky	Draft a list of HIPAA-related issues and proposed experts for future meetings	8/30/2004	
	Wendy Patterson	Redraft scenarios document and send out to David Fenstermacher	9/1/2004	
	David Fenstermacher	Add scenarios to use cases	9/12/2004	
	David Fenstermacher	Present use cases to other WS/WG		As schedule allows
	Phan Winter/ Wendy Patterson	Clarify SOW tasks for DSIC WG participants	9/2/2004	